

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Wolfgang HEIL et al.

Confirmation No.: 5622

Serial No.: 09/654,227

Examiner: M. Bandy

Filed: August 31, 2000

Group Art Unit: 1617

Title: PHARMACEUTICAL COMPOSITION FOR USE AS A CONTRACEPTIVE

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**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

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- ☐ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
 - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
 - ☐ before the mailing of a first substantive office action (including after filing of an RCE).
- ☒ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☒ a final rejection under 37 C.F.R. § 1.113;
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 - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR

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- ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
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☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

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- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
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CITED MATERIALS

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. _____, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated _____.
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- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
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OTHER INFORMATION

None

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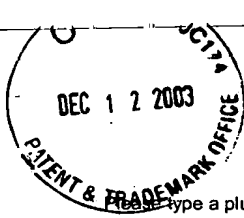
Respectfully submitted,


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Attorney Docket No.: PLOVIN-1A

Date: December 10, 2003



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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known

Application Number	09/654,227
Filing Date	August 31, 2000
First Named Inventor	Wolfgang HEIL et al.
Group Art Unit	1617
Examiner Name	M. Bahar
Attorney Docket Number	PLOVIN-1A

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A1	4,217,347		Horovitz et al.	08-12-1980
	A2	5,001,113		Williams et al.	03-19-1991
	A3	5,824,667		Spona et al.	10-20-1998
	A4	6,083,528		Elliesen et al.	07-04-2000
	A5	6,121,465		Mohr et al.	09-19-2000
	A6	RE37,564		Spona et al.	02-26-2002

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	B1	DE	3022337	A1	Eiger et al.	01-07-1982		
	B2	WO	95/07081	A1	Koninckx	03-16-1995		
	B3	WO	97/10827	A1	Petit et al.	03-27-1997		
	B4	WO	98/27929	A2	Nashed	07-02-1998		

NON PATENT LITERATURE DOCUMENTS

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	C1	Elstein et al., "Advances in Oral Hormonal Contraception," <i>Zentralbl Gynakol</i> 117 (1995) 559-565	
	C2	Oelkers et al., "Effects of the new progestogen and antimineralocorticoid dihydrospirorenone," <i>Acta Endocrinologica</i> 1992: 126 Suppl. 4, p. 71	
	C3	Oelkers et al., (1991) "Dihydrospirorenone, a New Progestogen with Antimineralocorticoid Activity: Effects on Ovulation, Electrolyte Excretion, and the Renin-Aldosterone System in Normal Women" <i>Journal of Clinical Endocrinology and Metabolism</i> , Vol. 73, No. 4, 837-842	
	C4	Oelkers, "Effects of oral contraceptives on the renin - aldosterone system: overview and report on a new natriuretic progestogen," <i>Advances in Contraception</i> , 7 Suppl. 3 (1991) 195-206	
	C5	Kincl et al., "Increasing Oral Bioavailability of Progesterone by Formulation," <i>Journal of Steroid Biochemistry</i> , 1978, Vol. 9, pp. 83-84	

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	C6	Whitehead et al., "Absorption and metabolism of oral progesterone," <i>British Medical Journal</i> , 22 March 1980, pp. 825-827	
	C7	Maxson et al., "Bioavailability of oral micronized progesterone," <i>Fertility and Sterility</i> , Vol. 44, No. 5, November 1985, pp. 622-626	
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	C13	Clarke et al., "Factors Influencing Comparative Bioavailability of Spironolactone Tablets," <i>Journal of Pharmaceutical Sciences</i> , Vol. 66, No. 10, October 1977, pp. 1429-1432	
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	C15	Berger et al., (1992) "Influence of Different Progestogens on Blood Pressure of Non-Anaesthetized Male Spontaneously Hypertensive Rats" <i>Contraception</i> 46: 83-97	
	C16	Skouby, (2000) "The rationale for a wider range of progestogens" <i>Climacteric</i> , Vol. 3, (Suppl. 2); 14-20	
	C17	Norman et al., (2000) "Drospirenone" <i>Drugs of the Future</i> 2000, 25(12): 1247-1256	
	C18	R. Krattenmacher, (2000) "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen" <i>Contraception</i> 62, 29-38	
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	C20	Parsey et al., (2000) "An Open-Label, Multicenter Study to Evaluate Yasmin, a Low-Dose Combination Oral Contraceptive Containing Drospirenone, a New Progestogen" <i>Contraception</i> , 61: 105-111	

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Sheet

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of

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C mplete if Known

Application Number 09/654,227

Filing Date August 31, 2000

First Named Inventor Wolfgang HENKEL et al.

Group Art Unit 1617

Examiner Name M. Bahar

Attorney Docket Number PLOVIN-1A

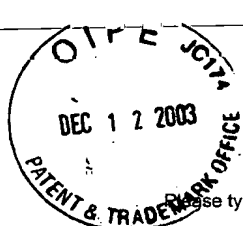
NON PATENT LITERATURE DOCUMENTS

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	C21	Krause et al., "Isolation and Identification of Spirorenone Metabolites from the Monkey (<i>Macaca Fascicularis</i>)," <i>Steroids</i> , Vol. 40, No. 1, July 1982, pp. 81-90	
	C22	Krause et al., "Determination of Plasma Levels of Spirorenone, a New Aldosterone Antagonist, and One of its Metabolites by High-Performance Liquid Chromatography," <i>Journal of Chromatography</i> , 230 (1982) 37-45	
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	C24	Wilson et al., (1984) "A prospective controlled study of the effect on blood pressure of contraceptive preparations containing different types and dosages of progestogen" <i>Brit. J. Obstet Gynecol</i> 91, 1254-1260	
	C25	Nichols et al., (1993) "Effect of four combined oral contraceptives on blood pressure in the pill-free interval" <i>Contraception</i> 47, 367-376 (1993)	
	C26	Oelkers et al., (1974) "Effects of Progesterone and Four Synthetic Progestagens on Sodium balance and the Renin-Aldosterone System in Man" <i>J. Clin. Endocrinol Metab</i> 39, 882-890	
	C27	Rylance et al., "Natural progesterone and antihypertensive action," <i>British Medical Journal</i> , Vol. 290, Jan. 5, 1985, p. 13-14	
	C28	Luotola, "Blood Pressure and Hemodynamics in Postmenopausal Women During Estradiol-17 β Substitution," <i>Annals of Clinical Research</i> , Vol. 15, Suppl. 38 1983	
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	C30	Rajkumar et al., "Hormonal Therapy Increases Arterial Compliance in Postmenopausal Women," <i>JACC</i> , Vol. 30, No. 2, August 1997:350-6	
	C31	Hayward et al., "Effect of hormone replacement therapy on non-invasive cardiovascular haemodynamics," <i>Journal of Hypertension</i> , 1997, Vol. 15, No. 9, p.987-993	
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	C34	Wren et al., "The effect of type and dose of oestrogen on the blood pressure of post-menopausal women," <i>Maturitas</i> , 5 (1983) 135-142	
	C35	Oelkers, "Reply to Letter to the Editor," <i>Gynecol Endocrinol</i> , 2000, 14:476-478	

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		Group Art Unit	1617
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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C36	Seely et al., "Estradiol With or Without Progesterone and Ambulatory Blood Pressure in Postmenopausal Women," <i>The American Heart Association, Inc.</i> , May 1999, 1190-1194
	C37	Mercuro et al., "Effects of Acute Administration of Transdermal Estrogen on Postmenopausal Women with Systemic Hypertension," <i>The American Journal of Cardiology</i> , Vol. 80, September 1, 1997, 652-655
	C38	"Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," <i>JAMA</i> , January 18, 1995, Vol. 273, No. 3, 199-208
	C39	Pripp et al., "A randomized trial o effects of hormone replacement therapy on ambulatory blood pressure and lipoprotein levels in women with coronary artery disease," <i>Journal of Hypertension</i> , 1999, Vol. 17, No. 10, 1379-1386
	C40	Manhem et al., "Transdermal oestrogen reduces daytime blood pressure in hypertensive women," <i>Journal of Human Hypertension</i> , (1998) 12, 323-327
	C41	Ittersum et al., "Ambulatory-Not Office-Blood Pressures Decline During Hormone Replacement Therapy in Healthy Postmenopausal Women," <i>American Journal of Hypertension</i> , 1998, Vol. 11, No. 10, part 1, 1147-1152
	C42	Carara et al., "Abstracts Thirtieth Annual Meeting American College of Clinical Pharmacology September 23-25, 2001, Vienna, Virginia," <i>J Clin Pharmacol</i> , 2001; 41:1014-1033
	C43	Epstein, "Aldosterone and the hypertensive kidney: its emerging role as a mediator of progressive renal dysfunction: a paradigm shift," <i>Journal of Hypertension</i> , 2001, Vol. 19, No. 5, 829-834
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	C45	Pitt et al., "The Effect of Sprionolactone on Morbidity and Mortality in Patients with Severe Heart Failure," <i>The New England Journal of Medicine</i> , Vol. 341, No. 10, September 2, 1999, 709-717
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